Although couched in the language of continuous quality improvement, the accreditation process is, at its core, a risk reduction activity. It begins with the setting of contemporary standards that address important organisational functions—for example, patient assessment, medication usage—and then encourages organisations, through the awarding of accreditation, to comply with these standards. The operating thesis is that if organisations are doing the "right things right," as reflected in the standards, then errors and adverse outcomes are less likely to happen than if there were no such standards. Notwithstanding the continued high frequency of errors, this thesis is almost certainly correct.[5]

We are simply at a more primitive stage than we would like to be in our knowledge of why what happens happens in healthcare organisations. It has become too easy to accept some (undefined) degree of medical errors as the inevitable byproduct of today's increasingly complex patient care and simply to blame and punish individual caregivers when things go seriously wrong. Leaders of the medical profession and of healthcare organisations do not include reducing medical errors among their top priorities. Because of this, the level of commitment to analysing relationships between errors and adverse outcomes on the one hand and organisational systems and processes on the other has so far been modest. There is now a growing urgency that such analyses should be undertaken and that the knowledge gleaned should be assimilated, shared, and used in designing and redesigning safer organisational infrastructures that minimise the potential impact of human factors in the delivery of care.[6]

Changing existing attitudes, behaviours, and priorities towards the identification and management of medical errors lies well beyond the "control" of accrediting bodies or regulatory agencies. Nevertheless, because of their roles as agents of public accountability, such external quality oversight bodies do have the ability to foster constructive change in healthcare organisations.

For example, largely through a voluntary self reporting system, the Joint Commission on Accreditation of Healthcare Organizations has developed a database of serious adverse events and of the results of organisational analyses of these events. We periodically share the lessons learnt with all accredited organisations.[7] This simple effort to translate negative results into useful information that can prevent errors in multiple settings is easily replicable anywhere in the world. Mandatory reporting of these occurrences and related analyses would rapidly produce an even richer database, but without the guarantee of confidentiality for the analyses (which does not currently exist) the evidence suggests[8] that the analyses would probably not be performed with the desired degree of thoroughness.

The joint commission has also recently introduced the requirement that each accredited organisation should establish reporting channels for unexpected adverse occurrences, perform an in depth analysis of each such occurrence, implement improvements, and assess the impact of the improvements on internal systems and processes. This should move error and adverse event management up leaders' priority lists and help accredited organisations begin to learn more about themselves.

In the end, however, what we most need is a characteristic not described by Hippocrates—the ability of care givers to admit and accept fallibility. Furthermore, the organisations in which care is provided must create environments in which it is "safe" to admit error and safe as well to explore why the error occurred. In a sense, we need to extend the peer review collegiality inherent in the classic morbidity and mortality conference to the context of the entire organisation. Simply stated, if we truly expect to improve the safety of patient care, those who directly provide the care must engage in the improvement process and feel safe in doing so.

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Why error reporting systems should be voluntary

They provide better information for reducing errors

Doctors, nurses, and pharmacists share a common goal of identifying medical error, understanding its causes, and making system wide changes to reduce medical risks. Error reporting is a primary component of that goal. Recent public policy discussions in the United States have explored the risks and benefits of mandatory and voluntary reporting systems to identify the most effective ways to promote candid disclosure of medical error.[1 2] The Institute for Safe Medication Practices has been a strong and vocal proponent of non-punitive, voluntary error reporting programmes.[3]

National models exist in the US for both mandatory and voluntary error reporting programmes. The Medication Errors Reporting Program, operated by the United States Pharmacopoeia in cooperation with the Institute for Safe Medication Practices, is a confidential, voluntary medication error reporting programme. About 1000 completed error reports are received each year from clinicians and state boards,

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but more important than the number of reports is their quality. Each report provides a great deal of information which has allowed us to identify the wide scope of medication safety problems and explore their system based causes. Practical recommendations to prevent reoccurrence are made through a widely distributed newsletter and other educational efforts.

The information derived from the programme has also allowed us to influence the pharmaceutical industry, device manufacturers, and regulatory bodies such as the Food and Drug Administration to change healthcare standards and medical product design. For example, after a series of accidents with cisplatin the institute persuaded manufacturers to include the maximum dose on phial caps and seals. Similarly, after repeated problems with accidental intrathecal injection of vincristine, manufacturers now place hazard warnings on phials, and dispensers place a special warning on the label of each syringe and on the syringe overwrap. There are many other examples where the institute has used data on errors to prompt manufacturers to change labelling, packing, and nomenclature and issue safety warnings.

The Safe Medical Devices Act of 1990 is an example of a mandatory reporting system. Healthcare facilities and manufacturers are required to report serious injury or illness related to the failure or misuse of specific medical devices. However, this federal act has been unsuccessful in gaining compliance with reporting requirements for user error. Furthermore, little action is taken unless significant numbers of harmful errors have been reported. Some states also have mandatory reporting programmes for error resulting in serious patient harm. Yet this information is used almost exclusively to punish individual practitioners or healthcare organisations.[1] There is little analysis of the systems causes of error, and the information is rarely used to warn others about the potential for similar errors.

As these and other examples show,[4 5] non-punitive and confidential voluntary reporting programmes provide more useful information about errors and their causes than mandatory reporting programmes. A major reason is that voluntary programmes provide frontline practitioners with the opportunity to tell the complete story without fear of retribution. The depth of information contained in these stories is key to understanding the error. Practitioners who are forced to report errors are less likely to provide in depth information because their primary motivation is self protection and adherence to a requirement, not to help others avoid the same tragedy. Voluntary programmes also encourage practitioners to report hazardous situations and errors that did not cause harm but have the potential to do so. It is not feasible to require reporting of such near misses, so critical information is lost and error prevention strategies are less likely.

The barriers to widespread reporting fall primarily into three categories: fear of individual or organisational repercussion; the false belief that medical error can be used as a measure of practitioners' competence; and potential legal discovery of error reports. Thus, a key factor in our quest for safer patient care is broader immunity for error reports and a non-punitive culture that places a higher value on resolving system based problems than on punishing practitioners for errors.

Most mandatory reporting programmes are designed to identify "bad" practitioners and facilities and punish them. This emphasis on individuals and on the error itself, not its correction, is a powerful deterrent to reporting. Even if mandatory programmes offer an amnesty or immunity to individuals, they often punish those who fail to report. Practitioners do not need to be forced to report errors. They just need freedom from punishment, which is possible only with a voluntary reporting programme.

Mandatory reporting programmes imply that the individual at fault must report the error. Yet analysis of serious errors always reveals multiple system failures and the involvement of many individuals. Who then must report the error? Is it the pharmaceutical company or medical device manufacturer whose product name, label, or design has repeatedly led to user error, or is it the practitioner involved? Which practitioner must report an error that started with an ambiguous prescription or a wrongly dispensed drug? By necessity, responsibility for mandatory reporting will probably fall on designated management staff. Managers may be less inclined or unable to communicate information beyond that which is required, even with statutory protection to minimise legal risks. Thus little useful information about the root causes of medical error will be secured.

Both mandatory and voluntary reporting programmes will prove futile in the absence of a strong, well designed system for analysis and response. To improve safety, reporting must be accompanied by effective, timely system changes that are upheld by accrediting bodies and regulatory agencies through standards that enhance patient safety. Likewise, reporting programmes should be managed by an independent, multidisciplinary, expert body that can objectively determine the system based causes of errors and promote effective change.

Reporting is fundamental to the broad goal of error reduction. However, barriers to reporting must be addressed before an incident reporting system can have a substantial impact on patient safety. Reporting will occur only if practitioners feel safe doing so and it becomes a culturally accepted activity within the healthcare community. Until health care embraces such a culture, practitioner reporting will continue to be an untapped resource.

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